UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

May 27, 2009

MEMORANDUM

Subject: Efficacy Review for Envirocleanse;
EPA Reg. No. 85134-R; DP Barcode: D363037

From: Marcie Tidd, Microbiologist Marcie Tidd 5/28/09
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To: Emily Mitchell PM 32 / Michael Hardy
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Applicant: Envirocleanse LLC
14019 SW Freeway #301-387
Sugar Land, TX 77478

Formulation from the Label:

Active Ingredient(s)	% by wt.
Hypochlorous Acid	0.025%
Other Ingredients	99.975%
Total	100.000%

I. BACKGROUND

The product, Envirocleanse®, is a new (Reg. No. 85134-R) hospital/medical use and general disinfectant (bactericide). The applicant is submitting data to support the use of the product as a general disinfectant. Testing was conducted by Microbiotest, Inc. located at 105B Carpenter Drive in Sterling Virginia.

The data package contained a letter from the applicant's representative to the Agency (dated February 12, 2009), the Confidential Statement of Formula, the Data Matrix, the proposed label (dated February 12, 2009), and one study (MRID 476867-03) with Statements of No Data Confidentiality and Good Laboratory Practice.

II. USE DIRECTIONS

The product is intended for use as a disinfectant in commercial, industrial, and household environments such as hotels, office buildings, restaurants, convenience stores, food processing plants, schools, playgrounds (indoor), day care centers, nursing homes, cafeterias, prisons, police stations, hospitals, pharmaceutical and medical device producing establishments, homes, condos, apartments, veterinarian clinics, and other facilities. The product is to be used on hard, non-porous surfaces such as countertops, sinks, toilets, tables, chairs, appliances desks, beds, floors, computer keyboards, door knobs, and similar surfaces.

The proposed label provides the following directions for use of the product as a disinfectant on hard, non-porous surfaces. Apply to surface with a cloth, mop, sponge or coarse sprayer. Wet the surfaces thoroughly and allow surface to remain wet for 10 minutes. Allow treated surface to air dry. For best results, remove gross soiling from surfaces before applying this product. Small non-porous objects can also be soaked in Envirocleanse without dilution. Allow objects to soak for 10 minutes.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments
The effectiveness of disinfectants for use on hard surfaces in hospital or medical environments must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products Test (for spray products). The tests require that sixty carriers must be tested with each of 3 samples, representing 3 different batches, one of which is at least 60 days old, against *Salmonella enterica* ATCC 10708 (for effectiveness against Gram-negative bacteria), *Staphylococcus aureus* ATCC 6538 (for effectiveness against Gram-positive bacteria), and *Pseudomonas aeruginosa* ATCC 15442 (representative of a nosocomial pathogen). [180 carriers per sample; a total of 540 carriers] To pass performance requirements, tests must result in killing in 59 out of each set of 60 carriers to give a 95% confidence level.

Supplemental Recommendations

Antimicrobial agents which claim to be "one-step" cleaner-disinfectants, or cleaner-sanitizers, or agents to be used in the presence of organic soil, must undergo appropriate efficacy testing modified to include a representative organic soil of 5% blood serum. A suggested method to simulate antimicrobial treatment of dry inanimate surfaces is to add the blood serum 5% v/v (19mL bacterial inoculum with 1mL blood serum) to bacterial inoculum prior to carrier contamination and drying. Control data should be produced as described in Supplemental Recommendation 6 of DIS/TSS-2 to confirm the validity of this test with this modification. The suggested organic soil level is appropriate for simulation of lightly to moderately soiled surfaces. For highly soiled surfaces, a prior cleaning step should be recommended on the product label. A suggested procedure for incorporating organic soil load where the antimicrobial agent is not tested against a dry inanimate surface, such as the AOAC Fungicidal Test involves adding 5% v/v blood serum directly to the test solution (e.g., 4.75 ml test solution + 0.25 ml blood serum) before adding 0.5 ml of the required level (5 X 10^6 /ml) of conidia. These agency standards can be found in DIS/TSS-2.

IV. SUMMARY OF SUBMITTED STUDY

MRID 476867-03 "AOAC Use Dilution Test, Healthcare" against Envirocleanse by Felicia L. Sellers. Study conducted by Microbiotest, Inc., Laboratory Project Number 668-103. Study completed January 29, 2009.

This test was conducted against *Salmonella enterica* ATCC 10708, *Staphylococcus aureus* ATCC 6538, and *Pseudomonas aeruginosa* ATCC 15442 following Microbiotest protocol 668.1.01.02.09 (included) according to the Official Methods of Analysis of the AOAC, Sixteenth Edition (2006). Three lots of the product were tested (Lot Nos. 1, 2, and 3 (over 60 days old at time of testing)). Heat inactivated horse serum was added to the bacterial inoculum to achieve a 5% organic soil load. The test substance was received ready-to-use. Stainless steel penicylinders were placed into 48-54 hour old cultures (at a ratio of 20 penicylinders per 20 mL of inoculum). Carriers were dried for 20-40 minutes at 37±2C then exposed to the test agent (10 mL per cylinder) for 10 minutes at 20C. Following exposure, carriers were transferred to individual tubes containing 10 mL of D/E Neutralizing Broth then thoroughly shaken and incubated for 48±2 hours at 37±2C. The test report indicates that because of the opacity of the neutralizer broth, *P. aeruginosa* cultures were streaked onto TSA plates and incubated 24±2 hours at 37±2C; results for growth and no growth will be determined based upon the streak plates [this procedure is congruent with the procedure for verification of positive carriers]. Controls included those for neutralizer effectiveness, viability, sterility, carrier count, bacteriostasis, and confirmation of the test organism.

V. RESULTS

MRID Number	Organism	Dried Carrier Count CFU/Carrier	No. Exhibiting Growth/Total No. Tested		
			Lot 1	Lot 2	Lot 3
476867-03	*Staphylococcus aureus* ATCC 6538	1.1×10^6	1/60	1/60	1/60
	Pseudomonas aeruginosa ATCC 15442	1.3×10^6	0/60	1/60	0/60
	Salmonella enterica ATCC 10708	1.2×10^5	1/60	1/60	1/60

VI. CONCLUSIONS

1. The submitted data (MRID 476867-03) support the use of the product, Envirocleanse, as a broad spectrum hard surface disinfectant at full strength in the presence of light organic soil at room temperature with a contact time of 10 minutes. Killing was demonstrated on at least 59/60 carriers per lot. Controls were acceptable for a valid test.

VII. RECOMMENDATIONS

1. The proposed label claims that the product, Envirocleanse, is an effective one-step hospital / medical and broad spectrum disinfectant in the presence of moderate organic soil (5% serum) at full strength with a contact time of 10 minutes on hard, nonporous surfaces. These claims are **acceptable** as they are supported by the submitted data.

2. The following recommendations are made regarding proposed label language.

    a. Currently directions for application and use of the product are included in one paragraph under use surfaces. Use instructions must be kept separate and clearly laid out for the user.

    b. The product is being registered as a hard surface disinfectant, yet includes use sites which are considered food-contact surfaces. The directions for use must be amended to include a potable water rinse on these surface post application and contact time.

    c. On page 2, remove the language "For best results..." from the statement, "For best results, remove gross soiling from surfaces before applying this product." This language implies that the removal of gross soil is optional, when in fact that

product has not been tested in 'gross soil,' and is not known to be effective in these conditions.

3. The applicant's cover letter indicates that this is a me-too application and that the product is substantially similar to Oculus Microcyn Sanitizer (Reg. No. 81206-1). The last accepted label for Oculus Microcyn Sanitizer lists an additional active ingredient not present on this product's label or CSF, and is in reduced concentrations. This reviewer advises the PM to review the submissions and their chemistry to ensure that these products are indeed substantially similar.

4. Historically, the Agency has not allowed antimicrobial products to carry claims of being environmentally friendly or "green." The name of this product, "Envirocleanse," could be misconstrued as environmentally preferable, especially in conjunction with certain packaging designs. This reviewer recommends that the PM consider this product name in light of this issue before issuing registration.